K043444
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FEB 2 2 2005

510(K) Summary

Submitter
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Crosslinks International
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Los Angeles, CA 90067
USA

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Manufacturer:
Golden Horse Medical Equipment (Wuxi) Co., Ltd.
42 Xi Xin Road, Zhang Jing Town,
Wuxi City, P. R. China 214194

Tel: +86 510 3791303
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Device Name:
Proprietary Name: Multiple
Common/Usual Name: Aneroid Sphygmomanometer
Device Name: Non-invasive Blood-pressure Measurement System
Product Code: DXN
Classification: Class II

Predicate Device:
Mabis brand and Mabis customers private label brand
Establishment: MABIS HEALTHCARE, INC.
Regulation Number : 890.5500
Product Code : DXN
510(k) Number: K942072
Registration Number: 1422443
Owner/Operator Number: 9005245

Description of the Multiple Brand KTJ-50:
The aneroid sphygmomanometer with stethoscope is a non-invasive blood pressure measurement system for

monitoring blood pressure levels which can be performed by trained individuals. The sphygmomanometer Model KTJ-50 consists of 5 parts. They are aneroid manometer, latex bulb, cuff, valve and stethoscope set. The aneroid sphygmomanometer with stethoscope enables the user places the attached stethoscope on the inner arm above the bend in the elbow, to detect the Korotkoff sound. After inflation of the cuff, the user does auditory monitor with the stethoscope to evaluate systolic and diastolic pressure. The two values are recorded as: systolic over diastolic.

Intended Use

The Multiple Brand KTJ-50 is an aneroid sphygmomanometer intended to be used for the indirect (noninvasive) measurement of the arterial blood pressure by trained medical and health care personnel or trained general users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 - 2005

Golden Horse Medical Equipment (Wuxi) Co., Ltd.
c/o Mr. George Su
Crosslinks International, Inc.
1800 Century Park East, Suite 600
Los Angeles, CA 90067

Re: K043444
Trade Name: Multiple, Model KTJ-50
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood-Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: February 09,2005
Received: February 10,2005

Dear Mr. Su:

This letter corrects our substantially equivalent letter of February 22,2005, regarding the regulation number, regulation name, and product code.

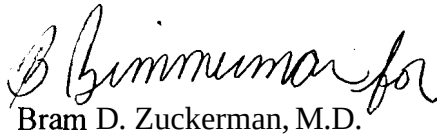
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class 11 (Special Controls) or class III (PMA). it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination doks not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0293. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043444

Indications for Use

510(k) Number(if known): K043444

Device Name: Non-invasive Blood Pressure Measurement System

Indications for Use:

The Multiple Brand, with model number *KTJ-50*, aneroid sphygmomanometer is an instrument intended to be used for the indirect (noninvasive) measurement of human's Systolic, Diastolic blood pressure using the auscultatory method by detecting Korotkoff Sound. This device is to be used by trained medical and health care personnel or trained general users.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043444

(Posted November 13, 2003)